UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

UNITED STATES OF AMERICA, EX REL., DOMINION DIAGNOSTICS, LLC, **Plaintiffs,** **v.** **CALLOWAY LABORATORIES, INC.; AIT LABORATORIES, INC., A/K/A AMERICAN INSTITUTE OF TOXICOLOGY, INC.; and AMERITOX, LTD.;** **Defendants.**	**FILED UNDER SEAL AS REQUIRED BY 31 U.S.C. § 3730 (False Claims Act Qui Tam)** **CIVIL ACTION NO.** 4:08cv282-RH/WCS **JURY DEMAND**

COMPLAINT

Relator-Plaintiff Dominion Diagnostics, LLC (hereinafter referred to as "Relator"), through its attorneys, brings this False Claims Act Complaint against Defendants Calloway Laboratories, Inc.; AIT Laboratories, Inc., a/k/a American Institute of Toxicology, Inc.; and Ameritox, Ltd. (hereinafter referred to as "Defendants").

I. NATURE OF THE CASE

1. Relator's case arises from the Defendants' violations of the False Claims Act, 31 U.S.C. §§ 3729-3733, and Relator brings this action on behalf of Relator and the United States Government pursuant to 31 U.S.C. § 3730(b).

2. Defendants to this action caused the submission and conspired with others to facilitate the submission of false and fraudulent claims for payment to the federal Medicare, Medicaid and Tri-Care programs through the submission of fraudulent and false billings for clinical laboratory and diagnostic testing services. In addition, Defendants falsely certified that

the Defendants were in compliance with all applicable laws and regulations regarding this provision of healthcare services, and that the clinical laboratory and diagnostic testing services for which they billed were provided in compliance with such laws and regulations, when Defendants knew they were in violation of the anti-kickback statute, 42 U.S.C. § 1320a-7b.

II. JURISDICTION AND VENUE

3. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732.

4. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 31 U.S.C. § 3732, because any one Defendant is found, resides, or transacts business, or acts proscribed by 31 U.S.C. § 3729 occurred, in this District. Defendants each transact business in this District.

III. PARTIES

5. Defendants are licensed clinical labs that bill Medicare, Medicaid, and/or Tri-Care and receive federal funds.

6. Relator is a clinical laboratory licensed by the State of Florida and is headquartered in Rhode Island. Relator is a competitor of Defendants herein and has obtained, through its field staff and others, direct and independent knowledge of the information on which the allegations of this Complaint are based. Relator has disclosed to the United States the facts surrounding the basis for its Complaint and is an original source of the information.

7. Defendant Calloway Laboratories, Inc. ("Calloway") is a clinical toxicological laboratory specializing in urine drug testing protocols for substance abuse screening and prescription drug compliance services. Calloway is a CLIA-certified laboratory and is licensed by the State of Florida as a clinical lab. Calloway is headquartered in Wakefield, Massachusetts, and does business in the State of Florida, including within the Northern District. Calloway bills

Medicare, Medicaid and/or Tri-Care for its clinical laboratory services and/or assists physicians who use its tests in billing Medicare, Medicaid and/or Tri-Care for their physician services.

8. Defendant AIT Laboratories, Inc., a/k/a American Institute of Toxicology, Inc. ("AIT") provides clinical laboratory and toxicological services for health care, pharmaceutical and forensic professions. AIT is headquartered in Indianapolis, Indiana, and does business in the State of Florida, including in the Northern District. AIT bills Medicare, Medicaid and Tri-Care for its clinical laboratory services and/or assists physicians who use its tests in billing Medicare, Medicaid and/or Tri-Care for their physician services.

9. Defendant Ameritox, Ltd. ("Ameritox") is a licensed clinical laboratory that provides drug testing and analysis. Ameritox markets its programs to pain management practitioners as a way of determining compliance with prescription regimens. Ameritox is headquartered in Midland, Texas, and is licensed as a clinical laboratory in the State of Florida and does business in the State of Florida, including in the Northern District. Ameritox bills Medicare, Medicaid and Tri-Care for its clinical laboratory services and/or assists physicians who use its tests in billing Medicare, Medicaid and/or Tri-Care for their physician services.

BACKGROUND

10. Defendants each are clinical, diagnostic and/or toxicological laboratories that primarily provide urine drug testing for substance abuse clinics and physicians who provide pain management treatments for patients suffering from long term chronic pain. Physicians use the Defendants' tests to determine whether patients are complying with treatment programs, whether patients who are receiving prescriptions of opiates for pain management are appropriately using their prescriptions, and also whether patients are taking non-prescribed drugs outside of the physician's prescription protocol.

11. Defendants will typically perform enzyme immunoassay tests on the urine samples sent by physicians to their laboratories. The results of these tests may also be confirmed by other tests performed by the Defendant. Each of the Defendants bills Medicare, Medicaid, and/or Tri-Care for those clinical laboratory, diagnostic and/or toxicological services if those programs cover the patient and will be reimbursed for those tests from federal funds.

12. In addition, physicians who receive test kits from the Defendants will also use those test kits to perform tests on the patient's urine and will bill Medicare, Medicaid and/or Tri-Care for those services if the patient is covered by one of the programs. In order to collect urine specimens from patients for testing, physicians must obtain specimen collection cups and other supplies necessary for the collection and shipment of samples to the laboratory.

13. Each of the Defendants engages in the marketing and sale of specimen collection cups to physicians. Single purpose collection cups cost approximately $.49 per cup; however, several of the Defendants also market what are known as "dual use" collection cups. In addition to allowing for the collection of urine specimens from patients for clinic laboratory analysis, the "dual use" collection cups also provide an instant "on-site" result for certain drug classifications. These "dual use" collection cups are read on-site, but are also sent to the clinical laboratory for further testing. Depending on the volume of cups purchased, "dual use" collection cups cost anywhere from $6.00 to $8.25 per cup.

IV. DEFENDANTS' FRAUDULENT SCHEMES

14. In order to induce physicians to use their clinical laboratory testing services, the Defendants employ a variety of inducements and remunerations to physicians. Defendants Calloway and AIT provide free "dual use" collection cups which ordinarily cost anywhere from

$6.00 to $8.25 per cup. These cups are provided to physicians without cost in order to induce the physician to use Calloway or AIT to conduct their clinical laboratory tests on those specimens.

15. For example, Defendant AIT advertises on its website that,

> "Another benefit of our test is costs. Where you might spend up to $10.00 per sample just for the instant test, (this does not include the cost of confirmation), our test is **free** to your practice, as we handle all the third party billing on our behalf of your office. This isn't a service that is available with a standard drugs of abuse test, insurance companies won't pay."

16. Defendant Ameritox does not provide free test cups, but they do provide physicians with free personnel to perform specimen collections in physician offices in the States of Florida, California and New York, and possibly other states. At least one purpose of providing such personnel without charge is to induce the physician to use Ameritox to perform clinical laboratory testing on that specimen.

17. During the period 2004 through at least 2008, Defendants submitted invoices to Medicare, Medicaid and/or Tri-Care for clinical laboratory services that were ordered by physicians who received the above-described kickbacks or unlawful inducements. Defendants also falsely certified that the services were provided in compliance with applicable laws and regulations, when each of the Defendants knew it was in violation of the anti-kickback statute 42 U.S.C. § 1320a.-7b.

18. Payment of kickbacks or the provision of unlawful inducements by Defendants resulted in the presentment of false claims to the Medicare, Medicaid and/or Tri-Care Programs by Defendants and their physician clients. In addition, payment of these kickbacks and provision of unlawful inducements resulted in Defendants and their physician clients falsely certifying that they were acting in compliance with pertinent laws and regulations when each submitted bills to Medicare. Certification is a condition for payment by Medicare.

COUNT I
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(1))

19. Relator incorporates by reference paragraphs 1 through 18 above.

20. Defendants each knowingly presented or caused to be presented false or fraudulent claims for payment to the federal Medicare, Medicaid and/or Tri-Care Programs.

21. Defendants knowingly submitted or caused to be submitted false or fraudulent certifications to Medicare, Medicaid and/or Tri-Care in which they certified or caused others to certify that Defendants were acting in compliance with all pertinent laws and regulations, when in fact Defendants were paying kickbacks in violation of numerous laws and regulations, including the Anti-Kickback Act, 42 U.S.C. § 1320a-7b.

22. Defendants, by and through their officers, agents, and employees, authorized their various officers, agents, and employees to take the actions set forth above.

23. The Government directly or indirectly through various state Medicaid programs made payments to Defendants based upon false and fraudulent claims and thereby suffered damages. The United States Government is entitled to full recovery of the amount paid by the Medicare, Medicaid and/or Tri-Care Programs pursuant to submission of false claims submitted or caused to be submitted by the Defendants.

24. As set forth in the preceding paragraphs, Defendants knowingly violated 31 U.S.C. § 3729(a)(1) and have damaged the United States by their actions in an amount to be determined at trial.

COUNT II
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(2))

25. Relator incorporates by reference paragraphs 1 through 18 above.

26. Defendants each knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the federal Medicare, Medicaid and/or Tri-Care Programs.

27. Defendants knowingly made or caused to be made a false statement in Medicare, Medicaid and/or Tri-Care billings in which Defendants certified or caused others to certify that Defendants were acting in compliance with all pertinent laws and regulations, when in fact Defendants were paying kickbacks in violation of numerous laws and regulations, including the Anti-Kickback Act, 42 U.S.C. § 1320a-7b.

28. Defendants, by and through their officers, agents, and employees, authorized their various officers, agents, and employees to take the actions set forth above.

29. The Government made payments to Defendants based upon false and fraudulent billings and certifications and thereby suffered damages. The United States Government is entitled to full recovery of the amount paid by the Medicare, Medicaid or Tri-Care programs pursuant to submission of false claims submitted or caused to be submitted by the Defendants.

30. As set forth in the preceding paragraphs, Defendants knowingly violated 31 U.S.C. § 3729(a)(2) and have damaged the United States by their actions in an amount to be determined at trial.

COUNT III
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(3))

31. Relator incorporates by reference paragraphs 1 through 18 above.

32. Each of the Defendants entered into an agreement with various non-party physicians to defraud the United States through knowingly paying kickbacks to physicians in return for the physicians ordering clinical laboratory services from Defendants and thereafter

misrepresenting compliance with all applicable laws and regulations in bills submitted to Medicare, Medicaid and/or Tri-Care. Through this conspiracy, Defendants and their co-conspirators increased their Medicare, Medicaid and/or Tri-Care billings and paid or received unlawful remuneration for ordering clinical laboratory services in violation of the anti-kickback statute, 42 U.S.C. § 3120a-7b.

33. Defendants, by and through their officers, agents, and employees, authorized their various officers, agents, and employees to take the actions set forth above.

34. The Government made payments to Defendants based upon false and fraudulent claims and thereby suffered damages. The United States Government is entitled to full recovery of the amount paid by the Medicare, Medicaid and/or Tri-Care Programs pursuant to submission of false claims submitted or caused to be submitted by the Defendants as a result of these conspiracies.

35. As set forth in the preceding paragraphs, Defendants and their co-conspirators knowingly violated 31 U.S.C. § 3729(a)(3) and have damaged the United States by their actions in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the Relator Dominion Diagnostics, LLC and the United States pray:

A. That this Court enter judgment under Counts I through III against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 or more than $11,000 for each action in violation of 31 U.S.C. § 3729, *et seq.*;

B. That the Relator be awarded all costs incurred, reasonable attorneys' fees and expenses;

C. That in the event the United States Government intervenes at the time the action is unsealed and proceeds with this action, the Relator be awarded an amount of at least 15%, but not more than 25%, of the proceeds of this action or settlement of the claims;

D. That in the event the United States Government does not intervene as set forth above, the Relator be awarded an amount of at least 25%, but no more than 30% of the proceeds of this action or settlement of the claims;

E. That the United States Government and the Relator receive all relief, both at law and in equity, to which they are entitled; and,

F. That a trial by jury be held on all issues.

Dated this 24th day of June, 2008.

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